



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0386]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments and Listing of Ingredients in Tobacco Products
AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0650. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments and Listing of Ingredients in Tobacco Products (OMB Control Number 0910-0650)--Extension

On June 22, 2009, the President signed the Tobacco Control Act (Public Law 111-31) into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 301 et seq.) by, among other things, adding a new chapter granting FDA important authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors.

Section 905(b) of the FD&C Act (21 U.S.C. 387e(b)), as amended by the Tobacco Control Act, requires that “every person who owns or operates any establishment in any State engaged in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products * * *” register with FDA the name, places of business, and all establishments owned or operated by that person. Every person must register by December 31 of each year. Section 905(c) of the FD&C Act requires that first-time persons “engaging in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products shall register

with the Secretary the name, places of business, and all such establishments of that person.”

Section 905(d) states that persons required to register under sections 905(b) or 905(c) shall register any additional establishment that they own or operate in any state which begins the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products. Section 905(h) addresses foreign establishment registration requirements, which will go into effect when regulations are promulgated by the Secretary. Section 905(i)(1) of the FD&C Act, as amended by the Tobacco Control Act, requires that all registrants “shall, at the time of registration under any such subsection, file with [FDA] a list of all tobacco products which are being manufactured, prepared, compounded, or processed by that person for commercial distribution,” along with certain accompanying consumer information, such as all labeling and a representative sampling of advertisements. Section 904(a)(1) of the FD&C Act (21 U.S.C. 387d(a)(1)), as amended by the Tobacco Control Act, requires each tobacco product manufacturer or importer, or agent thereof, to submit “a listing of all ingredients, including tobacco, substances, compounds, and additives that are * * * added by the manufacturer to the tobacco, paper, filter, or other part of each tobacco product by brand or by quantity in each brand and subbrand.” Since the Tobacco Control Act was enacted on June 22, 2009, the information required under section 904(a)(1) must be submitted to FDA by December 22, 2009, and include the ingredients added as of the date of submission. Section 904(c) of the FD&C Act also requires submission of information whenever additives, or the quantities of additives, are changed.

FDA issued guidance documents on both: (1) Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments (November 12, 2009; 74 FR 58298) and (2) Listing of Ingredients in Tobacco Products (December 1, 2009; 74 FR 62795)

to assist persons making such submissions to FDA under the Tobacco Control Act. While electronic submission of registration and product listing information and ingredient listing information are not required, FDA is strongly encouraging electronic submission to facilitate efficiency and timeliness of data management and collection. To that end, FDA designed the eSubmitter application to streamline the data entry process for registration and product listing and for ingredient listing. This tool allows for importation of large quantities of structured data, attachment of files (e.g., in portable document format (PDFs) and certain media files), and automatic acknowledgement of FDA's receipt of submissions. FDA also developed paper forms (Form FDA 3742--Registration and Listing for Owners and Operators of Domestic Tobacco Product Establishments and Form FDA 3743--Listing of Ingredients in Tobacco Products) as an alternative submission tool. Both the eSubmitter application and the paper forms can be accessed at <http://www.fda.gov/tobacco>.

In the Federal Register of May 3, 2012 (77 FR 26281), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment beyond the scope of this collection was received that discussed the importance of extending this collection.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

FDA Form/ Activity/Tobacco Control Act Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Form FDA 3742/Registration and Product Listing for Owners and Operators of Domestic Establishments (Electronic and Paper submission)/Sections 905(b), 905(c), 905(d) 905(h), or 905(i)	125	1.6	200	3.75	750

FDA Form/ Activity/Tobacco Control Act Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Form FDA 3743/Listing of Ingredients (Electronic and Paper Submissions)/Sections 904(a)(1) or 904(c)	125	1.6	200	3	600
Obtaining a DUNS Number (10% of total respondents)	8	1	8	0.50 (30 minutes)	4
Total					1,354

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Since this collection of information was last approved by OMB on December 2, 2010, its burden has decreased by 407,421 hours, from 408,775 to 1,354 reporting hours. This adjustment is a result of FDA experience over the past 2 years in the regulation of tobacco products and is based on the actual number of establishment registration and product ingredient submissions received during this time period. In 2010, when this collection was first published for public comment in the Federal Register, FDA attempted to determine the actual number of tobacco manufacturers by using the Security and Exchange Commission's Standard Industrial Classification (SIC) codes, which are identifying codes that appear in a company's EDGAR filings to show the company's type of business. When preparing the collection of information package for publication in 2010, the tobacco industry codes indicated that over 10,000 tobacco manufacturers existed under the SIC codes for tobacco products and cigarettes. However, upon further examination of these codes, it appears that the number of tobacco manufacturers was greatly inflated, as the SIC codes included tobacco retail in addition to tobacco manufacturers. In addition, no comments were received from the 2010 initial 60-day Federal Register notice regarding either the number of respondents or the number of reporting burden hours listed in the notice, so FDA used the collection's SIC-researched manufacturer numbers for this collection of information. Actual FDA registration and product listing report submissions and FDA

experience indicate in the past 2 years, the number of tobacco manufacturers required to register and list their products and ingredient listings is approximately 125, a substantial decrease from the number of potential respondents listed in 2010. By applying the revised number of manufacturers to the burden chart, the total burden for registration and listing now is currently estimated to be 1,354 reporting burden hours, much less than the 408,775 OMB-approved reporting burden hours stated in 2010.

Based on the actual number of registration and product ingredient listing reports received by FDA over the past 2 years, the number of expected annual responses is projected to decrease from 100,000 registration responses to 200 annual responses, and from 11,000 annual product ingredient listing responses to 200 annual product ingredient responses. The Agency bases its estimate on the actual number of registration and listing and product ingredient listing reports received, its experience with the submission of registration and listing requirements applicable to other FDA regulated products, and ongoing interactions with industry. FDA estimates that the submission of registration information as required by section 905 of the FD&C Act will remain at 3.75 hours per establishment. Based on the actual number of registration information submitted in the past 2 years and its experience, the Agency estimates that approximately 200 registrations will be submitted from 125 tobacco product establishments annually, for a total 750 hour burden (125 respondents x 1.6 responses per respondent x 3.75 hours per response).

FDA estimates that the submission of ingredient listing information as required by section 904 of the FD&C Act will remain at 3.0 hours per tobacco product. Based on the actual number of product ingredient listings submitted over the past 2 years and its experience, the Agency estimates that approximately 200 ingredient listings will be submitted from 125 tobacco

establishments, for a total 600 burden hours (125 respondents x 1.6 responses per respondent x 3.0 hours per response).

FDA estimates that obtaining a Dun and Bradstreet (DUNS) number will take 0.5 hours, and that 8 respondents (1 percent (1.25) of establishments required to register under section 905 and 5 percent (6.25) of submitters required to list ingredients under section 904) will not already have a DUNS number. The total burden, therefore, will be 4 hours (8 respondents x 1 response per respondent x 0.5 hours per response).

Total burden hours for this collection, therefore is 1,354 hours (750 + 600 + 4 hours).

Dated: July 30, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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